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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Guy Scott Bristol

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EXAMINER

FRENEL, VANEL

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/025,023	Applicant(s) BRISTOL, GUY SCOTT	
	Examiner Vanel Frenel	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 January 1974.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6142002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed on 12/19/01. Claims 1-74 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al (5,781,442) in view of Vasko (5,871,465).

(A) As per claim 1, Engleson discloses a computerized system providing for the management and configuration of one or more therapeutic substance infusion devices, comprising:

a server connected to an internetwork, said server further being connected to a database of patient information (See Engleson, Col.4, lines 24-67 to Col.5, line 33);

a remote suite of computer readable remote program code devices for support of said implanted medical devices connected through said internetwork (See Engleson, Col.11, lines 33-67 to Col.12, line 34) comprising:

a fourth computer readable remote program code device which provides a

communication connection between a clinician and a pharmacy (See Engleson, Col.4, lines 24-67).

Engleson does not explicitly disclose that the system having a first computer readable remote program code device provided for a user pertaining to the management of therapeutic substance infusion devices;

a second computer readable remote program code device which allows the user access to reports detailing therapeutic substance infusion device patient support and device replacement management;

a third computer readable remote program code device which allows a user access to literature and materials providing information concerning therapeutic substance infusion devices.

However, these features are known in the art, as evidenced by Vasko. In particular, Vasko suggests that the system having a first computer readable remote program code device provided for a user pertaining to the management of therapeutic substance infusion devices (See Vasko, Col.1, lines 9-48);

a second computer readable remote program code device which allows the user access to reports detailing therapeutic substance infusion device patient support and device replacement management (See Vasko, Col.3, lines 20-44);

a third computer readable remote program code device which allows a user access to literature and materials providing information concerning therapeutic substance infusion devices (See Vasko, Col.7, lines 25-63).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Vasko within the system of Engleson with the motivation of providing a remotely programmable infusion system which having a programmable protocol, the infusion system being remotely programmable by a remote touch-tone transceiver (See Vasko, Col.2, lines 59-62).

(B) As per claim 2, Vasko discloses the computerized system wherein the first computer readable remote program code device allows the user to register a therapeutic substance infusion device with a medical device manufacturer (See Vasko, Col.1, lines 18-42).

The motivation for providing the respective teachings of Engleson and Vasko are as discussed in the rejection of claim 1, and incorporated herein.

(C) As per claim 3, Vasko discloses the computerized system wherein the first computer readable remote program code device allows the user to provide feedback to a therapeutic substance infusion device manufacturer regarding the operation of the therapeutic substance infusion device (See Vasko, Col.1, lines 18-42).

The motivation for providing the respective teachings of Engleson and Vasko are as discussed in the rejection of claim 1, and incorporated herein.

(D) As per claim 4, Engleson discloses the computerized system wherein the first computer readable remote program code device allows the user to view a therapeutic

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substance infusion device's capabilities and interconnectivities (See Engleson, Col.9, lines 27-62).

(E) As per claim 5, Engleson discloses the computerized system wherein the second computer readable remote program code device allows the user to view a list of therapeutic substance infusion devices implanted in one or more patients and schedule events pertaining to these devices (See Engleson, Col.11, lines 16-50).

(F) As per claim 6, Engleson discloses the computerized system wherein the second computer readable remote program code device allows the user to view at least one patient's prescription history and medical history (See Engleson, Col.5, lines 26-33; Col.14, lines 22-42).

(G) As per claim 7, Engleson discloses the computerized system wherein the second computer readable remote program code device predicts a lifespan of the therapeutic substance infusion devices (See Engleson, Col.6, lines 1-25).

(H) As per claim 8, Vasko discloses the computerized system wherein the redicted lifespan is based on an algorithm provided by a therapeutic substance infusion device manufacturer (See Vasko, Col.1, lines 18-42).

The motivation for providing the respective teachings of Engleson and Vasko are as discussed in the rejection of claim 1, and incorporated herein.

(I) As per claim 9, Vasko discloses the computerized system wherein the algorithm performs calculations for therapeutic substance infusion device replacement based on information learned by therapeutic substance infusion device manufactures on therapeutic substance infusion devices in an existing patient population (See Vasko, Col.1, lines 18-42).

The motivation for providing the respective teachings of Engleson and Vasko are as discussed in the rejection of claim 1, and incorporated herein.

(J) As per claim 10, Vasko discloses the computerized system wherein the predicted lifespan includes a minimum life expectancy, a maximum life expectancy, and a predicted failure date for the therapeutic substance infusion device (See Vasko, Col.).

The motivation for providing the respective teachings of Engleson and Vasko are as discussed in the rejection of claim 1, and incorporated herein.

(K) As per claim 11, Engleson discloses the computerized system wherein the second computer readable remote program code device provides the user with a therapeutic substance infusion device replacement schedule to provide reminders of upcoming device replacement priorities (See Engleson, Col.14, lines 22-32).

(L) As per claim 12, Engleson discloses the computerized system wherein a server file or a web page is accessed to provide access to the literature and materials

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concerning the therapeutic substance infusion devices (See Engleson, Col.1, lines 43-60).

(M) As per claim 13, Engleson discloses the computerized system wherein the literature and materials is specifically targeted to the user's areas of interest (See Engleson, Col.8, lines 15-30).

(N) As per claim 14, Engleson discloses the computerized system wherein the fourth computer readable remote program code device allows the clinician to place orders or refills of a therapeutic agent on behalf of a patient (See Engleson Col.10, lines 18-67).

(O) As per claim 15, Engleson discloses the computerized system wherein the fourth computer readable remote program code device allows the user to change prescription orders of a therapeutic agent on behalf of a patient (See Engleson, Col.7, lines 1-29).

(P) As per claim 16, Engleson discloses the computerized system wherein the fourth computer readable remote program code device provides the user with an automated dosage calculator to provide predictive scenarios of contemplated treatment regimens (See Engleson, Col.8, lines 5-45).

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(Q) As per claim 17, Engleson discloses the computerized system wherein the fourth computer readable remote program code device provides the user with pump refill or prescription order reminders (See Engleson, Col.8, lines 46-65).

(R) As per claim 18, Engleson discloses the computerized system wherein at least one computer readable remote program code device is implemented as an Internet graphical user interface application portal (See Engleson, Col.8, lines 31-45).

(S) As per claim 19, Engleson discloses the computerized system wherein the graphical user interface is a user-configurable template (See Engleson Col.11, lines 50-67 to Col.12, line 21).

(T) As per claim 20, Engleson discloses the computerized system wherein the Internet graphical user interface is implemented with Java or HTML technologies (The Examiner interprets information which can include an on-line and real-time to be a form of Java or HTML technologies See Engleson, Col.6, lines 1-13).

(U) As per claim 21, Engleson discloses the computerized system wherein the server hosts a first computer readable server program code device for the entry of patient information into the database of patient information (See Engleson, Col.1, lines 5-33).

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(V) As per claim 22, Engleson discloses the computerized system wherein the server is further connected to a database of therapeutic substance infusion device information (See Engleson, Col.1, lines 5-60).

(W) As per claim 23, Engleson discloses the computerized system wherein the server further hosts a second computer readable server program code device for the entry of therapeutic substance infusion device information into the database of therapeutic substance infusion device information (See Engleson, Col.1, lines 5-60).

(X) As per claim 24, Engleson discloses the computerized system of claim 23, wherein the server is further connected to a database of user profiles (See Engleson, Col.5, lines 58-67 to Col.6, line 13).

(Y) As per claim 25, Engleson discloses the computerized system of claim 24, wherein the server further hosts a third computer readable server program code device for the entry of user profile information into the database of user profiles (See Engleson, Col.5, lines 58-67 to Col.6, line 13).

(Z) As per claim 26, Engleson discloses the computerized system wherein the server is further connected to a database of therapeutic agent information (See Engleson, Col.6, lines 52-67 to Col.7, line 12).

(AA) As per claim 27, Engleson discloses the computerized system of claim 26, wherein the server further hosts a fourth computer readable server program code device for the entry of therapeutic agent data into the database of therapeutic agent information (See Engleson, Col.6, lines 52-67 to Col.7, line 12).

(BB) As per claim 28, Engleson discloses the computerized system wherein the server hosts a fifth computer readable server program code device for the accessing and analysis of therapeutic agent data as applied to at least one specific patient (See Engleson, Col.6, lines 40-51).

(CC) As per claim 29, Engleson discloses the computerized system wherein the fifth computer readable server program code device determines compatibility with at least one therapeutic substance infusion device (See Engleson, Col.1, lines 5-60).

(DD) As per claim 30, Vasko discloses the computerized system wherein the therapeutic agent data comprises recommended dosages and agent interaction data (See Vasko, Col.12, lines 1-43).

The motivation for providing the respective teachings of Engleson and Vasko are as discussed in the rejection of claim 1, and incorporated herein.

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(EE) As per claim 31, Engleson, discloses the computerized system wherein the patient data further comprises therapeutic agent allergies for at least one specific patient (See Engleson, Col.6, lines 40-51).

(FF) As per claim 32, Engleson discloses the computerized system wherein the fifth computer readable server program code device provides therapeutic agent refill and order reminders (See Engleson, Col.8, lines 15-65).

(GG) As per claim 33, Engleson discloses the computerized system wherein access to the server is provided to third party users over a secure virtual connection over a public internetwork (See Engleson, Col.4, lines 41 to Col.5, line 33).

(HH) As per claim 34, Vasko discloses the computerized system wherein the third party users can be pharmacists, physicians, patients, or therapeutic substance infusion device manufacturers (See Vasko, Col.1, lines 18-42).

The motivation for providing the respective teachings of Engleson and Vasko are as discussed in the rejection of claim 1, and incorporated herein.

(II) As per claim 35, Vasko discloses the computerized system wherein the access to the server is provided following encrypted knowledge-based authentication (The Examiner interprets security measures to protect against unwanted programming of the

pump protocol to be a form of encrypted knowledge-based authentication See Vasko, Col.7, lines 25-48).

The motivation for providing the respective teachings of Engleson and Vasko are as discussed in the rejection of claim 1, and incorporated herein

(JJ) As per claim 36, Vasko discloses the computerized system wherein the access to the server is provided following receipt of a passphrase over an encrypted channel (The Examiner interprets security measures to protect against unwanted programming of the pump protocol to be a form of a passphrase over an encrypted channel See Vasko, Col.7, lines 25-48).

The motivation for providing the respective teachings of Engleson and Vasko are as discussed in the rejection of claim 1, and incorporated herein

(KK) As per claim 37, Engleson discloses the computerized system wherein access to the server is provided over a secure socket layer protocol connection (The Examiner interprets Ethernet cabling to be a form of secure socket layer protocol connection See Engleson, Col.15, lines 1-31).

(LL) As per claim 38, Engleson discloses the computerized system wherein the connection of the server to the internetwork is a business-to-business connection with at least one therapeutic agent dispensary (See Engleson, Col.15, lines 10-31).

(MM) As per claim 39, Engleson discloses the computerized system wherein the connection of the server to the internetwork is a business-to-customer connection with at least one physician (See Engleson, Col.5, lines 14-57).

(NN) As per claim 40, Engleson discloses the computerized system wherein the connection of the server to the internetwork is a business-to-customer connection with at least one patient (See Engleson, Col.5, lines 34-57).

(OO) As per claim 41, Engleson discloses a computerized system providing for the management and configuration of one or more therapeutic substance infusion devices, comprising:

- a server connected to an internetwork (See Engleson, Col.11, lines 33-67 to Col.12, line 34);

- a database of patient information connected to said internetwork (See Engleson, Col.11, lines 33-67 to Col.12, line 34);

- a database of therapeutic substance infusion device information connected to said internetwork (See Engleson, Col.11, lines 33-67 to Col.12, line 34);

- a database of therapeutic agent information connected to said internetwork (See Engleson, Col.11, lines 33-67 to Col.12, line 34);

- a database of user profile information connected to said internetwork (See Engleson, Col.11, lines 33-67 to Col.12, line 34);

- a suite of computer readable remote program code devices for support of said

implanted medical devices connected through said internetwork (See Engleson, Col.11, lines 33-67 to Col.12, line 34); including:

a fourth computer readable remote program code device that allows a clinician to communicate with a pharmacy wherein the clinician can place orders or refills of a therapeutic agent on behalf of a patient (See Engleson, Col.4, lines 24-67).

Engleson does not explicitly disclose that the computer system having a first computer readable remote program code device that allows a user to manage therapeutic substance infusion devices, said first application allowing the user to register a therapeutic substance infusion device with a medical device manufacturer;

a second computer readable remote program code device that allows the user access to reports detailing therapeutic substance infusion device patient support and device replacement management, said second application further allowing the user to view a list of therapeutic substance infusion devices implanted in one or more patients and schedule events pertaining to these devices;

a third computer readable remote program code device which allows a user access to literature and materials providing information concerning therapeutic substance infusion devices, said literature and materials being specifically targeted based upon user profile information.

However, these features are known in the art, as evidenced by Vasko. In particular, Vasko suggests that the computer system having a first computer readable remote program code device that allows a user manage therapeutic substance infusion

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devices, said first application allowing the user to register a therapeutic substance infusion device with a medical device manufacturer (See Vasko, Col.1, lines 9-48);

a second computer readable remote program code device that allows the user access to reports detailing therapeutic substance infusion device patient support and device replacement management, said second application further allowing the user to view a list of therapeutic substance infusion devices implanted in one or more patients and schedule events pertaining to these devices (See Vasko, Col.1, lines 18-57);

a third computer readable remote program code device which allows a user access to literature and materials providing information concerning therapeutic substance infusion devices, said literature and materials being specifically targeted based upon user profile information (See Vasko, Col.7, lines 25-63).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Vasko within the system of Engleson with the motivation of providing a remotely programmable infusion system which having a programmable protocol, the infusion system being remotely programmable by a remote touch-tone transceiver (See Vasko, Col.2, lines 59-62).

(PP) As per claim 70, Engleson discloses the computerized system wherein a therapeutic substance infusion device manufacturer administers the server (See Engleson, Col.4, lines 24-63).

(QQ) As per claim 74, Engleson discloses a computerized system providing for the management and configuration of one or more therapeutic substance infusion devices, comprising:

a server connected to an internetwork (See Engleson, Col.11, lines 33-67 to Col.12, line 34);

a database of patient information connected to said internetwork (See Engleson, Col.11, lines 33-67 to Col.12, line 34);

a database of therapeutic substance infusion device information connected to said internetwork (See Engleson, Col.11, lines 33-67 to Col.12, line 34);

a database of therapeutic agent information connected to said internetwork (See Engleson, Col.11, lines 33-67 to Col.12, line 34);

a database of user profile information connected to said internetwork (See Engleson, Col.11, lines 33-67 to Col.12, line 34);

said server hosts a first computer readable server program code device for the entry of patient information into the database of patient information (See Engleson, Col.5, lines 58-67 to Col.6, line 13);

said server hosts a second computer readable server program code device for the entry of therapeutic substance infusion device information into the database of therapeutic substance infusion device information (See Engleson, Col.5, lines 58-67 to Col.6, line 13),

said server hosts a third computer readable server program code device for the

entry of user profile information into the database of user profiles (See Engleson, Col.5, lines 58-67 to Col.6, line 13);

said server hosts a fourth computer readable server program code device for the entry of therapeutic agent data into the database of therapeutic agent information (See Engleson, Col.5, lines 58-67 to Col.6, line 13);

a suite of computer readable remote program code devices in communication with said server for support of said implanted medical devices connected through said internetwork including:

a fourth computer readable remote program code device that allows a clinician access to a pharmacy wherein the clinician can place orders or refills of a therapeutic agent on behalf of a patient (See Engleson, Col.4, lines 24-67).

Engleson does not explicitly disclose that the computer system having a first computer readable remote program code device that allows a user to manage therapeutic substance infusion devices, said first computer readable remote program code device allowing the user to submit therapeutic substance infusion device performance data and register a therapeutic substance infusion device with a medical device manufacturer so that the medical device manufacturer can inform users of important therapeutic substance infusion device issues (See Vasko, Col.1, lines 9-48);

a second computer readable remote program code device that allows the user access to reports detailing therapeutic substance infusion device patient support and device replacement management, said report providing a list of therapeutic substance infusion devices implanted in one or more patients, a

schedule of events pertaining to these devices, and an estimated lifetime of the therapeutic substance infusion device;

a third computer readable remote program code device which allows a user access to literature and materials providing information concerning therapeutic substance infusion devices, said literature and materials being specifically targeted based upon user profile information.

However, these features are known in the art, as evidenced by Vasko. In particular, Vasko suggests that the computer system having a first computer readable remote program code device that allows a user to manage therapeutic substance infusion devices, said first computer readable remote program code device allowing the user to submit therapeutic substance infusion device performance data and register a therapeutic substance infusion device with a medical device manufacturer so that the medical device manufacturer can inform users of important therapeutic substance infusion device issues;

a second computer readable remote program code device that allows the user access to reports detailing therapeutic substance infusion device patient support and device replacement management, said report providing a list of therapeutic substance infusion devices implanted in one or more patients, a schedule of events pertaining to these devices, and an estimated lifetime of the therapeutic substance infusion device (See Vasko, Col.1, lines 18-57);

a third computer readable remote program code device which allows a user access to literature and materials providing information concerning

therapeutic substance infusion devices, said literature and materials being specifically targeted based upon user profile information (See Vasko, Col.7, lines 25-63).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Vasko within the system of Engleson with the motivation of providing a remotely programmable infusion system which having a programmable protocol, the infusion system being remotely programmable by a remote touch-tone transceiver (See Vasko, Col.2, lines 59-62).

(RR) Claims 42-73 recite the underlying process steps of the elements of claims 3-4, 6-12, 15-19, 21, 23-24 and 26-40, respectively. As the various elements of claims 3-4, 6-12, 15-19, 21, 23-24 and 26-40 and have been shown to be either disclosed by or obvious in view of the collective teachings of Engleson and Vasko, it is apparent that the systems disclosed by the applied prior art performs the recited underlying functions. As such, the limitations recited in claims 42-73 are rejected for the same reasons given above for the system claims 3-4, 6-12, 15-19, 21, 23-24 and 26-40, and incorporated herein.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not the applied art teaches real time ambulatory patient monitor (5,544,661), medical treatment apparatus and method (5,895,371) and

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transportable modular patient monitor (5,375,604), Hospitals signing up quickly for cardiac implant device for transplant candidates; Anonymous. Hospitals Materials Management. Ann Arbor: Jan 1999. Vol.24, Iss.1; pg.5; Pages 1-2, St. Jude Medical Implants First Genesis System; Innovative Therapeutic Breakthrough for Treating CHF and AF by PR Newswire .New York: Feb 10, 2000 and therapy management techniques for an implantable medical device (2005/0021297).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is 571-272-6769. The examiner can normally be reached on 6:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

V.F
V.F

May 11, 2006


C. LUKE GILLIGAN
PATENT EXAMINER